CONTINUOUS INTRAPARTUM FETAL SCALP TISSUE pH AND ECG MONITORING BY A FIBEROPTIC PROBE

Howard M. Hochberg, M.D.
Paul V. Roby, M.D.
Hattie M. Snell, R.N.
W. Dean Smith, B.S.
International Biomedics, Inc., Bothell, Washington 98021

Molly S. Chatterjee, M.D.
Our Lady of Mercy Medical Center, Bronx, N.Y. 10466

Introduction

Labor and delivery can rapidly change from a normal to a potentially high risk situation. Accordingly, careful monitoring of mother and fetus has become the standard of care. Continuous electronic "fetal" monitoring (EFM) of fetal heart rates and uterine contractions is used almost universally in the United States. EFM information is sensitive to the possibility of dangerous deficits in fetal oxygen supply. However EFM data yields about 50 to 60% false positive "diagnoses" of significant fetal hypoxia (1) and may not detect up to 15-20% of true hypoxia. The most specific index of prolonged and potentially dangerous insufficient oxygen delivery is fetal blood pH (BpH); measured from drops of blood carefully collected from a small incision on the fetal scalp. The combination of BpH and EFM data reduces the incidence of false positives, while also improving detection of true problems. These combined data can be used to substantially reduce the Cesarean section rate for fetal distress (1-4). It is estimated that BpH information may be clinically important in up to 25% of patients (3,5).

However, BpH data is not commonly available because of the skills, time, inconvenience and laboratory facilities needed to obtain reliable measurements. Further one BpH measure is insufficient to

determine the trend of fetal pH (5). Finally, the tools and methods are primitive and there is some fetal risk (2). For all these reasons, and despite its potential value, BpH has not become the standard of practice in the United States.

The information inherent in the BpH measurement could be made widely available if there were a convenient safe probe to continuously monitor intrapartum fetal pH. This paper describes an investigational fetal pH probe designed to be safe and convenient. *At this time, the goal of the device is to provide reliable fetal pH status and trend data for use as an adjunct to EFM and BpH data for clinical care.*

Historical Perspective

The first fetal pH probe to undergo widespread clinical trials was the Stamm tissue pH (tpH) probe, designed for monitoring the pH of the subcutaneous fluid in the fetal scalp (6,7). Several studies demonstrated the validity of the basic concept of Stamm: human fetal acid-base balance can be monitored and evaluated by continuous monitoring of the scalp tpH (8-12). Clinical utility included a reduction in operative intervention for deliveries (9). However the Stamm device required sterile assembly and charging with sterile reference electrolyte a scalp incision for probe insertion and mastery of a difficult technique for apply and fixing the probe to the fetal scalp. The system was found to be impractical and the technique unreliable for routine clinical use.

In order to help to make these potentially valuable fetal tpH data generally available the authors and clinician investigators are evaluating a system and tpH probe designed to be convenient, safe, and reliable for continuous monitoring of fetal pH status. Fiberoptic, electro-optic, microprocessor and analytic chemistry technologies were integrated to produce a feasibility system designed for evaluation of continuous clinical monitoring of the fetal pH status during labor: The OBpH™ 1000 System. Using the experience gained

in monitoring over 300 patients between late 1983 through mid 1985, a total system designed to be convenient and simple for routine use by the clinician was designed and built. The latter system, the OBpH 1500, is in evaluation at this time. This paper describes the OBpH 1500 system and outlines clinical results from the earlier OBpH 1000 system, which used the same tpH probe.

Because this is an unreleased FDA Class III Investigational Devise in evaluation for regulatory purposes, International Biomedics can make no claims regarding safety, effectiveness or utility of the system. Further, it should be understood the device is designed as an adjunct to EFM and fetal scalp blood sampling, not as a total replacement for either measurement. (1987)

System Description

The OBpH 1500 System includes a fetal scalp pH ECG probe, an applicator tool, an electro-optic Interface module, an off-line Calibration chamber, and a fetal monitor for data display (Figures 1,2). The probe is a 22 gauge spiral ECG electrode which includes a fiberoptic-based pH sensor (Fig. 3,4). The probe is applied to the fetal scalp with the same general technique used for spiral ECG electrodes. When properly placed within the scalp, the pH sensor is within the subcutaneous fluid and the probe detects both subcutaneous fluid (tissue) pH and fetal ECG.

The probe is supplied in a sterile pack, with the tpH sensor within pH 7.00 buffer. After insertion of the probe pack and connector into the Interface, and insertion of the Interface into the Calibrator, the probe is automatically warmed, stabilized, stored and calibrated within the sterile pack. PH 7.36 Calibration is begun by depressing a sealed plunger through the cover of the sterile probe pack. The Calibrator checks for problems, confirms the reliability of the calibration, and the probe is ready for use within about 15 minutes. The calibrated probe can be used with confidence for up to 8 hours.

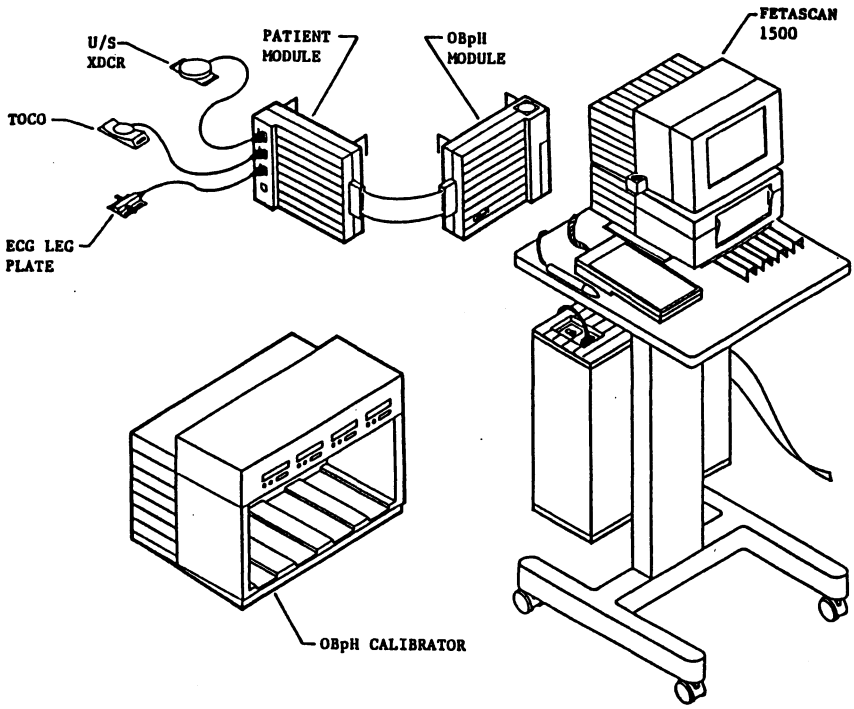
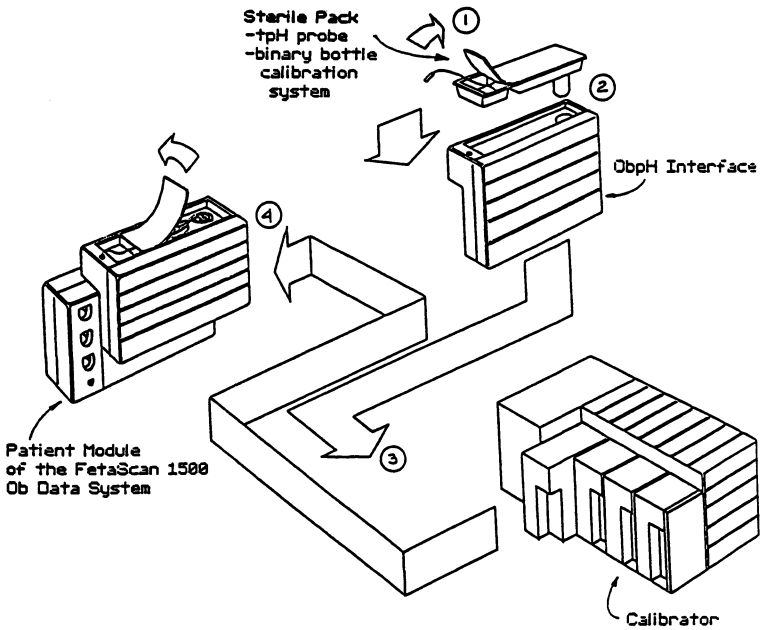


Figure 1 **The OBpH 1500 System**

This illustrates the bedside monitoring configuration of the system. The OBpH Module (Interface), an electro-optic and memory module which can contain the OBpH probe set. The OBpH Interface mates with the Patient Module of the FetaScan 1500. This assembly can be placed at the bedside, as the Patient Module accepts the ECG leg plate cable and uterine contraction transducers and the OBpH Interface can include a calibrated probe ready for use.

The OBpH Interface acquires and retains the probe calibration data, allowing the patient to be disconnected from the monitor for transport by disconnecting the Interface from the Patient Module.



Instructions

(1) Open connector chamber of sterile pack. Insert connector into tpH Interface.

(2) Insert sterile pack into tpH Interface.

(3) Insert tpH interface into Calibrator. Allow for stabilization, calibrate ten minutes before needed.

(4) When calibrated, remove Interface from calibrator, connect Interface to patient module. Probe is ready to use.

Figure 2 **Preparation of the Model 1500 OBpH System**

The OBpH 1500 Interface mates with either the calibrator or the monitor. It acquires and retains the probe calibration data, allowing the patient to be disconnected from and reconnected to any appropriate FetaScan 1500 monitor by disconnecting and reconnecting the interface, without disconnecting the probe.

The OBpH probe is in a sterile sealed package and it can be fully calibrated in this package without impairing sterility. Once calibrated, it can be placed at the bedside ready for use. The semiautomatic Calibrator holds 4 probe-interface packages ready for final calibration and use.

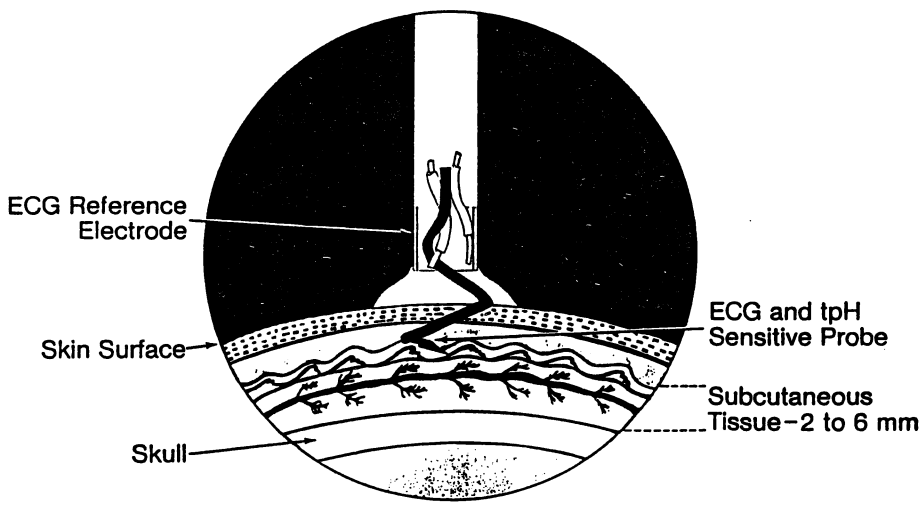


Figure 3

Drawing of the tpH probe in situ in the fetal scalp, with the applicator tool attached. The spiral forms one pole of the ECG electrode and the hub is the other. The tpH sensor window is just below the skin surface, facing into the subcutaneous tissue in order to measure the pH of the interstitial fluid.

Fiberoptic pH Probe Design

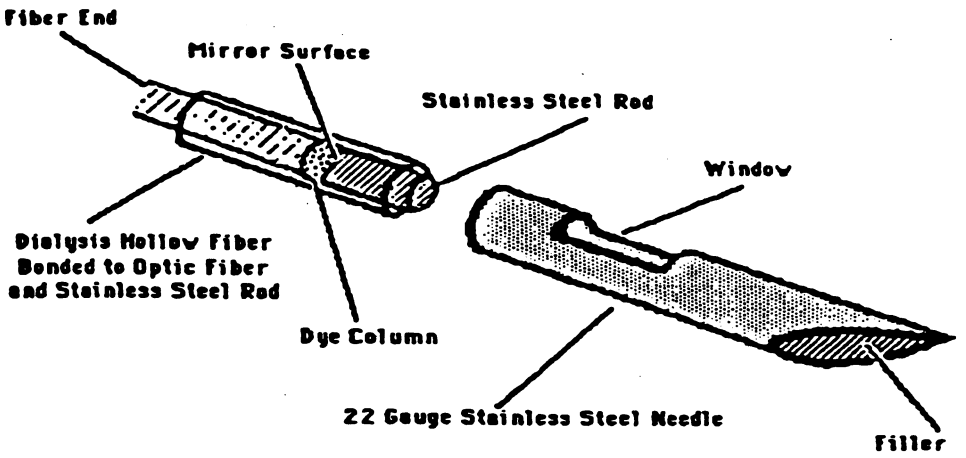


Figure 4 **Principle of Operation of the Fiberoptic pH Probe**

The above assembly is inserted into the solution to be measured. Protons (H+) diffuse freely through the dialysis hollow fiber into the dye column. The column contains a reversible pH-sensitive non-toxic dye covalently bound to a gel matrix (to prevent escape of dye). A fiberoptic fiber guides light to the dye, and directs reflected light to the instrument. There the green reflectance, the red reflectance, and the current with no light (dark current) are measured. The absorbance of green light by the dye is proportional to the pH in the range of interest, while red absorbance is not affected by pH. The red relectance is used as a reference signal.

The Interface module, with probe still attached, is then moved to the bedside. The pack is opened and the probe applied to the fetal scalp. The interface module is then attached to the FetaScan monitor, which automatically acquires and merges the tpH with the monitoring data on its strip chart and the video display, and continuously checks the validity of the optical data in order to flag problems (Fig. 5).

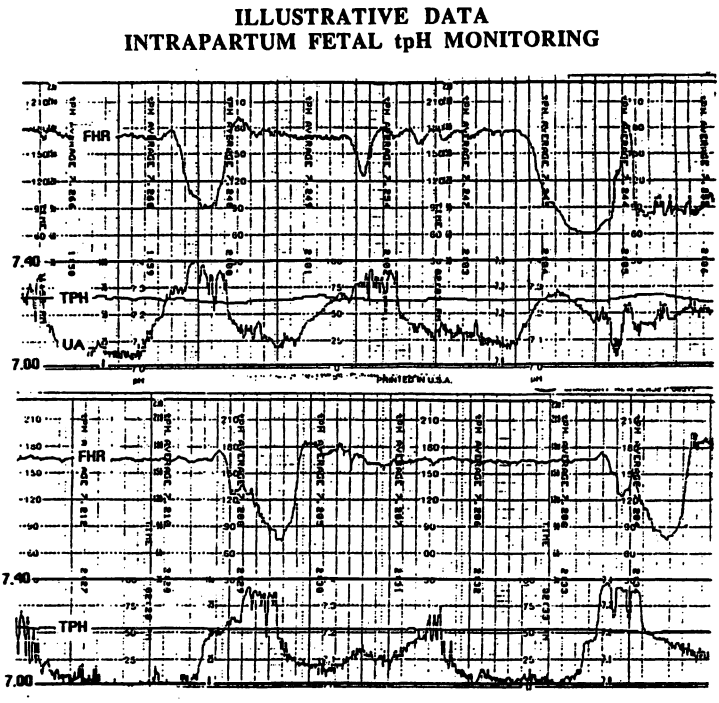


Figure 5 **Chart Display of Simultaneous Fetal Monitor and OBpH Data**

The fetal heart rate (FHR) demonstrates significant decelerations concordant with uterine activity (UA). The UA channel includes a tpH scale which ranges from pH 7.00 (bottom of record) to 7.40 (top of UA channel). The tpH is displayed as a linear graph on the UA channel, and it is updated every 20 seconds with the average tpH for the past 20 seconds. Each minute the average tpH is printed on the FHR channel (vertical printed statements). The FetaScan video displays the 20 second updated tpH value.

In-Vitro Performance of the OBpH System

In order to be useful as a trend monitor the OBpH system must resolve changes in pH at least as well as the current technology: the BpH. The 95% confidence interval (ci) of the BpH measurement is reported to be 0.06 pH or greater, with a non-Gaussian distribution (13,14). In-vitro studies of the OBpH probe demonstrate the 95% ci is 0.03 pH (Fig. 6). The absolute accuracy is within ±0.05 pH of a blood gas analyzer, which is also within the 95% confidence limits of blood measurement. Published data (8,15) show the high degree of correlation R>0.9 with in-vitro measurements of human fetal and adult blood.

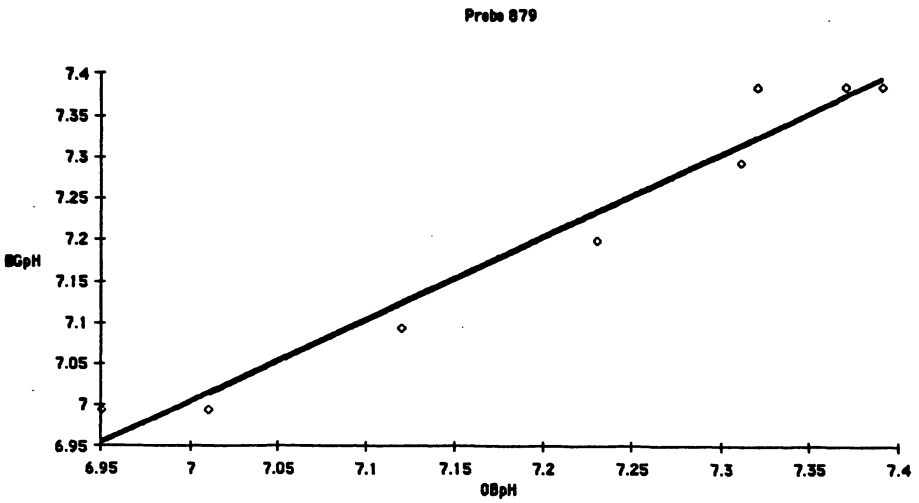


Figure 6 **Reproducibility of pH Measurement with a Single Fiberoptic tpH Probe**

The OBpH 1500 data is compared to blood gas analyzer pH (BGpH) at eight data points. The probe is first calibrated and then immersed in buffers of six other pH, and it is recycled through all eight pH at least twice. The probe must reproduce each data point within a bandwidth of ±0.03pH.

Clinical Investigational Plan

The feasibility model 1000 OBpH system was used in eight U.S. centers to monitor over 300 term or post-date high risk patients where BpH was indicated. The BpH was used to document the reliability of the current technology, the BpH, in following trends and to validate the reliability and the OBpH monitor in following trends of fetal pH status and in classifying fetal pH status as normal vs. not-normal.

The study goals:

1. Document the incidence of fetal or maternal problems caused by the OBpH in order to compare its safety with current technology.
2. Measure the *inherent* reliability of the tpH data for monitoring fetal pH status. "Inherent" means both the BpH and the OBpH data were unflawed or untainted, according to the investigator's report and an independent non-clinician reviewer at International Biomedics.
3. Document the perceived added value and clinical relevance of the OBpH monitoring data, when used as an adjunct to EFM and BpH measurements.

Clinical Study Methods

- Subject selection criteria:
  - Term or post-date patients in labor with vertex fetal presentation, and sufficient dilation and station to properly place the probe.
  - A documented indication for fetal scalp blood sampling for pH measurements.
  - No contraindications to fetal scalp blood sampling for pH measurements.
  - Informed consent given.

- Study Population: (Table I)

TABLE I
Study Population

	OBpH 1000	OBpH 1500
Total Patients	296	30
Total Formal Reports	291	30
Average Maternal Age	25 years	25 years
Average Gestational Age	39.9 wks	40.5 wks
Average Duration of OBpH Monitoring	2.0 hours	2:23 hours
Indications for pH Monitoring (% Cases)		
Abnormal FHR	83%	39%
Meconium	32%	28%
Post-date	21%	40%
Hypertension	16%	4%?
Diabetes	6%	---
Other	46%	36%
Pertinent Medications (% Cases)		
Oxytocin	42%	27%
Magnesium Sulfate	12%	-0-
Tocolytics	3%	-0-
Mode of Delivery (% Cases)		
Spontaneous Vaginal	61%	83%
Cesarean section	26%	17%
Forceps	11%	-0-
Vacuum	1%	-0-
No data	1%	-0-

TABLE I (CON)
Study Population

	OBpH 1000	OBpH 1500
Neonatal Problems		
Nuchal cord	9%	10%
Respiratory difficulties	3%	3%
Meconium aspiration	3%	-0-
Other	7%	-0-
One Minute Apgar Scores		
- 3	6%	-0-
4-6	18%	-0-
7-10	78%	100%
Adverse Effects	3.8%	-0-

• "Qualified Data Analysis" was used to measure the intrinsic reliability of the OBpH to monitor (correlate with) fetal CpH measurements, given no experimental flaws or "tainted data" and given the inherent variability of the CpH data. The correlation of replicate fetal CpH measures was determined in order to quantify the reliability of the current technology. Next, the tpH-CpH correlation data were calculated for those data points with replicate CpH, and then for all qualified sets of related tpH-CpH (Table II).

• "Physiological Data Analysis" was used to measure the clinical reliability of OBpH in trending fetal pH status, as measured by the correlation coefficient, given no obvious problems known to the investigator and pH values in the system operating range 7.09-7.44. (Tables II & III).

• Reliability of classification of fetal CpH by the OBpH data. These data included the predictive value of a normal tpH (7.20-7.44) vs. a normal CpH (7.25+) and the accuracy of both normal and not normal tpH to respectively predict normal & not normal CpH (efficiency of

tpH). These data quantified the reliance the clinician can place as the tpH reflecting the CpH status. (Tables II & III).

• Success in obtaining a reliable OBpH trend record as compared to the success of obtaining reliable CpH measurements was measured. Certain conditions are known to interfere with blood pH and fetal scalp ECG reliability because free access to the scalp is blocked, and these similarly interfere with OBpH probe fixation. The most notable in this study was thick matted fetal hair. Meconium, scalp edema and duration of monitoring or labor did not consistently interfere with OBpH or BpH data.

• The potential clinical relevance of the OBpH data in patient management in addition to the FHR and BpH data was reported on the data forms and tallied.

TABLE II
Reliability of the OBpH 1000 Data (Feasibility Model)

Total Case Reports with CpH and OBpH Data	198	
	Correlation Coefficients	
	Weighted Mean	Range (among Institutions)
Qualified Data		
BpH/BpH: Blood pH reliability: (excluding Corometrics 220 Analyzer CpH data)	r=0.81	r=0.71-0.90
OBpH/BpH (Trending reliability):	r=0.84	r=0.72-0.94
Reliability of Classification of BpH by OBpH 1000 Data		
Unflawed Physiological Data:	n=213 pairs.	
Predictive Value of Normal tpH:	100%	
False normal tpH:	0%	
Efficiency (correct class./total):	68%	

TABLE III
Reliability of the OBpH 1500 Data

Total Case Reports with both CpH and OBpH Data	20 (2 institutions)	
	Correlation Coefficients	
	Weighted Mean	Range
Physiological Data		
BpH/BpH: Blood pH reliability:	Insufficient Data	
OBpH/BpH:	r=0.89	r=0.79-0.93

Reliability of Classification of BpH by OBpH 1500 Data

Unflawed Physiological Data:	n=20 pairs
Predictive Value of Normal tpH:	100%
False Normal OBpH:	-0-
Efficiency (correct class/total):	89%

Success in Obtaining Fetal pH Data

The clinical experience demonstrated a continuous OBpH monitoring record could be obtained as frequently as a single valid fetal scalp blood pH data point (80%). With the OBpH 1500, the process was perceived to be simpler than obtaining one set of fetal scalp blood pH data point.

Clinical Relevance of the OBpH Data

The OBpH data was perceived as clinically relevant in 65% of these case reports. The most commonly mentioned advantages were:

•**Reassurance of fetal pH stability and normalcy, especially despite other changes suggestive of possible fetal deterioration.** (Abnormal FHR, Thick Meconium) This impression was validated by the 100% predictive value of a normal tpH.

•**Avoiding extra fetal scalp blood samples.**

•**Detecting trends in pH before they can be resolved by the blood pH method.** (Because of the OBpH self consistency)

•**Using the OBpH record as a guide to timing fetal scalp sampling for blood pH.** Usually there is no clear-cut indication as to when the pH is changing and may need diagnostic confirmation. The OBpH trend uniquely provides this information.

•**Monitoring fetal pH status where it is impractical to obtain timely repetitive blood pH data.** This is particularly relevant during stage II of labor, when abnormal heart rate patterns are common.

Discussion and Conclusions

The data demonstrated the OBpH system and the tpH method was inherently capable of reliable monitoring of fetal pH status, albeit with a different absolute value. The inherent consistency of the OBpH was obscured by the variability of the current technology, the BpH, the additional inter-institutional difference in BpH reliability; and possibly by clinical factors such as thick fetal hair. Also, there is an initial learning curve effect. At the start of the program, the correlation coefficient of tpH to OBpH was about 0.6. The last studies revealed correlation coefficients of 0.8 to 0.95 with a few or no tainted data points. Throughout the study, there were no false normal tpH values. When the tpH was 7.25 to 7.44, the unflawed BpH was always in the normal range.

Most clinicians perceived the data from the OBpH system to be clinically relevant, especially in monitoring trends of fetal pH status during worrisome events or events where repetitive timely BpH cannot be obtained. The investigators also immediately perceived the reliability of a normal and stable OBpH record.

To date, the clinical results obtained from the OBpH 1500 system are encouraging with respect to both practicality and reliability of the data.

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